SEP 2 9 2004

K042361
Page 1 of 2

EXHIBIT 2
510(k) Summary

SEDECAL SA Pelaya 9- Poligono Industrial Rio De Janeiro 28110 –Algete Madrid Spain Tel (34) 91-628 0544/91-628 1592 Fax (34) 91-628 0574 (Foreign Manufacturer)	SEDECAL USA, Inc. 2910 N. Arlington Heights Rd. Arlington Heights Illinois 60006 Tel 847-394-6960 Fax 847-394-6966 (Initial Importer) Contact: Devan Moser

August 24, 2004

1. Identification of the Device:
   Proprietary-Trade Name: SPS-HF-4.0-D Portable X-ray Units with Detector
   Classification Name: Mobile X-ray system, Product Codes 90 IZL and MQB
   Common/Usual Name: Portable general purpose diagnostic X-ray Unit.

2. Equivalent legally marketed devices: Sedecal Portable X-Ray Units K020435 and Canon CXDI-50G Digital Radiography, K031447. The MODIFIED device COMBINES these two units.

3. Indications for Use (intended use) The Sedecal Portable X-ray Units with Detector are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

4. Description of the Device: SPS-HF-4.0-D Portable X-ray Unit with Detector is a portable unit which operate from 120 V 50-60~ AC. The unit utilizes a high frequency inverter mounted to a tripod or support arm. The usual safety precautions regarding the use of x-rays must be observed by the operator. This modified device combines two FDA cleared devices by way of a common user interface, a color LCD touch panel. The X-Ray generator is controlled by a serial port on the CANON CXDI-50G.

5. Safety and Effectiveness, comparison to predicate device. The results of bench, user, and standards testing indicates that the new device is as safe and effective as the predicate devices.

K042361
Page 2 of 2

6. Substantial Equivalence Chart, The Sedecal Portable X-ray Units with Detector

Characteristic	Model SP-HF-4.0 K020435	Canon CXDI-50G Digital Radiography, K031447	Sedecal SPS-HF-4.0-D Portable X-ray Units with Detector (Combination device)
Intended Use:	Potable general purpose diagnostic X-ray unit	SAME	SAME
Size	8.7 H x 10.4" W x 16.5" D	Imaging Area 14 x 17	SAME (Combined device) (A stand has been added)
Weight	33 lb	10.6 lb	207 lb.
Energy Source:	90 to 285 VAC (50-60 Hz)	100V, 120V, 230/240V(50/60Hz)	SAME (Combined device)
User Interface	Up-Down pushbuttons for kVp and mAs. kVp adjustable in 1 kVp steps	Software Driven Touch Panel LCD	SAME (Combined device)
Exposure times	0.001-10 sec 41 steps	N/A	SAME (Combined device)
Ma.	5, 6.4, 8, 10, 12.5, 16, 20, 25, 32, 40, 50, 64, 80, 100	N/A	SAME (Combined device)
KvP	40 to 115 in 1 kVp steps	N/A	SAME (Combined device)
Resolution	N/A	160 x 160 microns pixel pitch, with approximately 6 million pixels and 4,096 gray scale contrast	SAME (Combined device)
Method of Control	Dedicated Touch Panel	Software Driven Touch Panel LCD	SAME as CANON. Or original Dedicated Touch Panel
Performance Standard	21 CFR 1020.30	SAME	SAME
Electrical safety:	UL 2601, IEC 60601-1	SAME	SAME

7. Conclusion

After analyzing bench, user, and standards testing data, it is the conclusion of Sedecal that the Sedecal Portable X-ray Units with Detector are as safe and effective as the predicate devices, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEDECAL SA
% Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

AUG 2 3 2013

Re: K042361
Trade/Device Name: Sedecal SPS-HF-4.0-D Portable X-Ray Units with Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB and IZL
Dated: August 30, 2004
Received: September 2, 2004

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of September 29, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042361

Device Name: Sedecal SPS-HF-4.0-D Portable X-Ray Units with Detector

Indications For Use:

Indications for Use: Sedecal Portable X-Ray Units with Detector are intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.

Prescription Use X (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legarm

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042361